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ENVIRONMENTALLY SOUND MANAGEMENT OF BIOTECHNOLOGY

Progress Report of the Secretary-General of the Conference

I. INTRODUCTION

1. At its First Substantive Session, the Preparatory Committee, in decision 1/17, requested the Secretary-General of the United Nations Conference on Environment and Development to: follow closely the progress in the work of relevant international organizations on safety in biotechnology, with a view to expediting the elaboration of basic guidelines and facilitating the preparation of an international Code of Conduct; report on the progress in deliberating of an international legal instrument on biological diversity; and prepare a report on the methodologies and procedures that could be used internationally to assess biotechnology risks, inter alia, to human health and the environment and the impact on socio-economic conditions. The reports are to be made available at the Third Session of the Preparatory Committee.

2. The Secretary-General believes it would be useful to provide a progress report to the Preparatory Committee at its Second Session; to keep the Committee informed on the status of the major activities undertaken at various fora, as well as propose potential areas for further action. This would ensure that the subsequent reports prepared will incorporate the views and guidance received.

3. In preparing the report the Secretary-General has worked in close collaboration with the relevant agencies of the United Nations system, drawing upon their relevant work, for example, the UNIDO/WHO/UNEP/FAO Informal Working Group on Safety in Biotechnology; the World Health Organization programmes in developing biosafety guidelines; the United Nations Industrial Development Organizations affiliated Centres for Genetic Engineering and Biotechnology; the Food and Agriculture Organizations work on Code of Conduct and the joint consultation with WHO on food safety; the United Nations Environment Programme and the United Nations Education Science and Culture Organizations Microbiological Centres; the Organization for Economic Cooperation and Development's extensive programme on safety and risk assessment of genetically modified organisms.

The Secretary-General has also received information from non-governmental organizations, which are involved in a wide array of activities related to biotechnology trends and their potential impacts. The recent work of some of the international non-governmental organizations are briefly provided to give an indication of the scope of the work.

4. In keeping with the request of the Preparatory Committee the Secretary-General has initiated a review of current work on biotechnology safety as well as developing procedures that could be used internationally to assess biotechnology risks. These are reported briefly below.

5. The Secretary-General has received valuable advice and assistance from members of the informal *ad hoc* Working Party in the work on environmentally sound management of biotechnology.

II. REVIEW OF CURRENT ACTIVITIES ON BIOTECHNOLOGY SAFETY

The UNIDO/WHO/UNEP/FAO Informal Working Group on Safety in Biotechnology

6. The Group, established since 1985, held its fourth meeting at UNIDO Headquarters, Vienna, Austria, in December 1985. The recommendations included, (i) evolvement of practical safety guidelines, whether new or adapted from existing guidelines, whether new or adapted from existing guidelines, that would be accepted internationally, (ii) establishment of regional advisory groups on biotechnology safety, (iii) preparation of an educational manual on biotechnology safety, (iv) preparation of an international Code of Conduct. The Group expressed the need for adequate funds to carry out these activities. The fifth meeting of the informal working group will be hosted by WHO in Geneva, May 1991.

The World Health Organization

7. Over the past three years, biosafety guidelines have been developed for workers engaged in the production of vaccines and biologicals; diagnostic and research laboratories working with HIV; and a chapter on safety in gene technology laboratory in the WHO Laboratory Safety Manual. Biological substances proposed for use in the public health sector and subject for consideration by the WHO Report Committee on Biological Standardization and Safety Task Forces have been established for evaluation of new vaccines. A programme for rapid diagnosis of infectious diseases and preparation of diagnostic reagents was established, and five centres in Asia and Africa are involved in the production of diagnostic reagents. The network of WHO Collaborating Centres on Biosafety has initiated a training programme on biotechnology safety. WHO and UNEP are also collaborating in a programme on safety for vaccine development.

The United Nations Industrial Development Organisation

8. Activities are implemented both by UNIDO and the International Centre of Genetic Engineering and Biotechnology (ICGEB). ICGEB consists of two laboratories in Trieste and New Delhi, and a network of Affiliated Centres. It maintains a permanent staff focusing mainly on agrobiology and human health with special reference to the problems of the developing countries. ICGEB is monitoring policies and trends in its member countries, and is codifying information on existing regulatory frameworks in order to set up an on-line database. A computer network, ICGEBnet, has been set up to provide the means of combining dispersed researchers, resources and information into a single integrated system.

8.1 UNIDO is about to initiate a project on the harmonization of existing guidelines on biotechnology safety and assessment methodologies on the release of genetically modified organisms to the environment, to begin in January 1991. The objective of the project is to provide the basis of uniform standards in risk assessment methodology and risk management. Its expected output is a set of documents consisting of a report on the harmonisation of existing national guidelines on biotechnology safety; a UNIDO position paper on a Code of Conduct for the release of genetically engineered organisms and plants into the environment; terms of reference for an advisory group for referral purposes for countries which do not have relevant safety guidelines and a manual reviewing all aspects of biotechnology safety.

The Food and Agriculture Organization

9. An FAO/WHO consultation on assessment of biotechnology in food production and processing as related to food safety has just been held, and further attention will be given to this aspect by the FAO/WHO Codex Alimentarius Commission. A Code of Conduct on biotechnology is under preparation containing elements of biosafety including release of genetically modified organisms and distribution of biotechnologically derived products useful for agricultural development.

The United Nations Environment Programme and the United Nations Education and Culture Organization

10. Since 1974 UNEP and UNESCO have established eight Regional Microbiological Resources Centres (MIRCENS) in developing countries. Each centre consists of a network of collaborating laboratories and institution, with one acting as a coordinating centre. Each MIRCEN maintains a regional genebank of microbial resources and serves as a centre of excellence for microbial conservation, utilization, research and training. These centres provide the mechanism for promoting biotechnology safety.

The Organization for Economic Co-operation and Development, OECD

11. The OECD is undertaking both follow-up work to the 1986 Council Recommendation concerning Safety Considerations for Application of Recombinant DNA Organisms in Industry, Agriculture and the Environment. New activities include the large scale introduction of genetically modified organisms (GMO's) to the environment; the safety of new foods and food components; and risk-based classifications of GMO's based on a review of risk assessment carried out to date by OECD member countries. The work is managed by several OECD directorates and is overseen by the Group of National Experts on Safety in Biotechnology. Documents on an elaboration of Criteria and Principles for Good Industrial Large Scale Practices (GILSP) and on

Good Developmental Principles. Guidance for the Design of Small-Scale Field Research with Genetically Modified Plants and Micro-Organisms will become publicly available in the very near future. Work on the Monitoring of GMO's released into the Environment is continuing and the report of an OECD Workshop, held in Denmark in December 1990, will be available in the near future. The document provides an account of the current state of the art on monitoring of organisms, genetic material and environmental processes with particular regard to the introduction of GMO's to the environment. Finally, OECD has just published an International Survey of Biotechnology Use and Regulations. Work on this survey led to the development of an OECD computerised pointer system, BIOTRACK, which lists information concerning over 260 releases of GMO's to the environment. This system is being updated yearly and will soon be publicly available in diskette form.

International Non-Governmental Organizations

12. An increasing number of non-governmental organizations are undertaking activities relating to biotechnology safety and risks. To give an indication of the range and scope being carried out, some examples, are given below:

12.1 The Stockholm Environment Institute, SEI, organized a Biosafety Workshop in December 1990 to consider the possibility of organizing an independent international biosafety panel to provide advice on request with respect to the release of transgenic organisms to the environment, the participants suggested that the concept be broadened to an advisory panel on agricultural biotechnology, and such a panel be created at once. The scope of the panel, structure, organization and possible modalities for implementation were discussed and recommendations made.

12.2 The International Organization of Consumer Unions (IOCU) has been actively exchanging information and networking with its members and other NGOs around the world on various aspects of biotechnology focusing on concerns for safety, environmental and social impacts of the technology and public input to decision making. In 1987, IOCU helped draft the "Bogeve Declaration", one of the first global NGO statements on biotechnology which expressed the need for safety in all process and applications, and in the same year IOCU itself adopted a resolution which called on "relevant international agencies and governments to take measures to achieve appropriate regulatory mechanisms and infrastructure to provide sufficient checks and safeguards on the development, testing, use, control and patenting of biotechnology products and processes". In the Netherlands, in May 1990, IOCU held a seminar on consumers and biotechnology which reinforced concerns over safety and called for the establishment of a working group that would gather data on the development of various applications, regulatory measures and other aspects of biotechnology in particular countries.

12.3 The Genetic Resources Action International, GRAN, secretariat amongst other work, provides a permanent contact point for information exchange amongst a network of groups and individuals throughout Europe and around the World, monitors closely the latest trends in biotechnology, and the impacts, including socio-economic, in developing countries.

III. PROGRESS IN DELIBERATIONS ON AN INTERNATIONAL LEGAL INSTRUMENT ON BIOLOGICAL DIVERSITY (1/17b)

13. At the third session of the *ad hoc* Working Group of Experts on Biological Diversity convened by the United Nations Environment Programme and held in Geneva in July 1990, the meeting felt that the nature of biotechnology elements for possible inclusion in a framework convention required further expert examination. The Sub-Working Group on Biotechnology met in Nairobi in November 1990. The Sub-Working Group recommended a number of issues that should be considered in the preparation of a biotechnology component in a global framework legal instrument on biological diversity.

14. The importance of building upon the work of existing organisations, structures and expertise and avoiding duplication was recognised. The need for assessment of risks and environmental impacts associated with biotechnology applications, especially release of GMO's, was commented upon. The need to develop institutional and human resources to take care of the special needs of developing countries in addressing their problems and developing relevant technologies was stressed. There was general agreement that the question of intellectual property rights should be reflected in the proposed convention, taking into account the problems of developing countries. Views were expressed that resolution of the issues should be left to those forums already dealing with this matter. It was suggested by some that GATT should be requested not to terminate its work on intellectual property rights until *inter alia* environmental and socio-economic aspects related to biotechnology, indigenous knowledge and traditional innovation had been thoroughly examined.

15. The Sub-Working Group noted that other bodies were already dealing with biotechnology risk, and while some felt that the proposed convention should address risks, others felt that the work of the other relevant bodies should be incorporated at a later stage. The meeting agreed that the inclusion of biotechnology issues into the proposed convention has already been decided in the decision adopted by the Governing Council, as well as in a recommendation by the *ad hoc* Working Group of Experts on Biological Diversity. The links between biotechnology and biomaterial justified the inclusion of biotechnology in the proposed convention.

IV. AN INTEGRATED PROGRAMME ON THE ENVIRONMENTALLY SOUND MANAGEMENT OF BIOTECHNOLOGY

16. The Preparatory Committee requested the Secretary-General to Prepare a report on methodologies and procedures that could be used internationally to assess biotechnology risks. A review of the methodologies and procedures that are being used to assess biotechnology risks and promote safety is being undertaken in the work

programme of the Secretariat. This will form a basis for developing methodologies and procedures that could be used internationally, which may include a Code of Conduct for transfer and application of biotechnology.

17. The Preparatory Committee may wish to consider an integrated programme, which would include risk assessment and biotechnology applications that could promote sustainable forms of development. This programme should strengthen and augment the on-going activities on biotechnology, which are increasing significantly. The Preparatory Committee may wish to consider the suggestions and provide guidance to the secretariat for the further elaboration of the integrated strategy.

18. Biotechnology has the potential to play an important role in sustainable development, health protection and improving human well being. It offers an opportunity for increasing co-operation between countries that have rich genetic resources and those that have the technologies to use these resources for development to improve the standard of living and quality of life for the people. Between now and the end of the century, world population will grow by nearly 1000 million. At the same time, more farm land is expected to be lost to urbanisation and environmental degradation. To provide food for everyone, crop production must expand by three percent per annum, with most of the increase coming from higher productivity of existing farmland. World food security will therefore depend on the breeding of better adapted and higher yielding food crops. This is not an impossible task - between 1960 and 1980, cereal yields increased by about 750kg per hectare, due largely to new cultivars. There will also be a need to increase and improve public health protection and care, in which biotechnology will also play an important role, with applications such as the development of candidate vaccines, immunodiagnostics, DNA probes for important diseases, improved drug delivery systems, probes for genetic diseases, production of polyclonal and monoclonal antibodies and suitable expression systems.

19. Biotechnology applications for sustainable development could contribute to many of the UNCED priority themes:

- Combatting deforestation;
- Preventing soil loss, desertification and drought;
- Conservation and sustainable use of biological diversity;
- Protection of freshwater and marine resources;
- Environmentally sound management of wastes and toxic chemicals;
- Rural development and human settlements;
- Protection of the atmosphere, climate change.

20. There is also a need to develop guidelines that could be provided for biotechnology research and application, on issues that may raise ethical and social concerns. This would help assuage public concerns, encourage acceptance of new endeavours, and provide guidance to research work. The guidelines could also be inputs for the development of the Earth Charter.

21. Due to the important role of biotechnology in environment and development, the Preparatory Committee may wish to consider an integrated programme that would address both the safety/risk aspects as well as the applications of biotechnology.

Main Environment and Development Issues to be Considered

Issues in Risk Assessment and Risk Management

22. In biotechnology, it is not known whether adverse effects to the environment are to be expected with the application of genetically modified organisms (GMO's). The need for a careful review prior to application is based on the fact that there is limited experience with this type of organism and that possible adverse effects may be irreversible. Several industrialised countries have recognised the need for a preventative approach, and have prepared guidelines and legislation for the application of GMO's. To provide an internationally accepted basis for risk management, in 1986 the OECD published the Recombinant DNA Safety Considerations. In April 1990, the European Community adopted two Directives on the use of genetically modified organisms.

23. A review of existing safety procedures, regulations and programmes in the world shows the general approach. The contained use of GMO's may be regulated on the basis of the classification of risk categories and safety procedures that have evolved after 20 years of experience with contained use. Releases of GMO's into the environment are reviewed on a case by case basis and conducted in a step by step manner, because insufficient data are present to permit any classification on the possible releases of GMO's. The differentiation between contained use and release will continuously evolve towards higher degrees of categorisation. It should be noted that the explicit mention of GMO's does not mean that GMO's are intrinsically dangerous. The focus on GMO's is due to the limited experience with their application and the potential for the novel role they might play in the environment. The design of safety procedures may allow their application to organisms other than GMO's, such as non-modified pathogens, introduced exotics or non-indigenous organisms.

24. There are a number of other issues that need to be considered. These include:

- The need for international harmonisation of codes in biotechnology. National borders are no defence against risk, given the possibility of transport by air, water, animals, insects et cetera;

- The special needs of developing countries, both in terms of insufficient technical expertise and management experience, and particular features of an environment and its associated ecosystem;

- The need to extend codes of practice beyond containment within the laboratory to include transportation of genetically modified material between laboratories;

- The need for assessment of biotechnology to look beyond the measurable financial costs and benefits to also include socio-economic impacts;

- The need to apply risk assessment methods to the transfer and release of exotic non-modified organisms as well as GMO's;

- The recognition that compliance systems required for GMO detection could be extremely large. The preparation of a Code of Conduct should therefore investigate a system of notification that risk assessment has been done and other methods to overcome enforcement difficulties;

- The recognition that implementation of a Code of Conduct will require increased levels of specialised technical skill. This will be a particular bottleneck in developing countries, and training programmes will be required.

Issues in the Application of Biotechnology

25. Ensuring adequate supplies of safe and nutritious food produced in sustainable agricultural systems in developing countries will be an increasingly difficult challenge in the years ahead. Rapid population growth, plant, human and animal diseases, and accelerating environmental deterioration are some of the important factors mitigating against increased food production in many of the developing countries. During the past thirty years, great strides in agricultural production have been achieved through plant breeding, soil and water conservation, irrigation, fertilizers and other improved agronomic practices. In developing countries as a whole, wheat and rice production increased by approximately 75 percent between 1965 and 1980. Impressive as these gains are, new tools are required to supplement conventional plant breeding and protection. Among the new tools are applications of biotechnology such as recombinant DNA. Some of these are now in use or in field trials in industrialised countries. These products have considerable potential for overcoming constraints to increased food production in developing countries, for example by reducing large-scale losses caused by viruses through development of virus-resistant plants.

26. Unlike the dwarf varieties of rice and wheat in the "Green Revolution", the new life science technologies are increasingly proprietary, owned by corporations and public research institutions, largely in industrialized nations. Accordingly, technology transfer will have to be facilitated from both public and private sector in the industrialized countries to the developing countries. Current investment in biotechnology research and development is approximately $11 billion per annum, of which 75% is private sector (particularly multinational companies). Many of the superior future applications will also be proprietary, and the role of the private sector will increase as developing country market economies develop and the level of industrialisation increases. Industry is especially strong at delivering products to the market place, but in many countries the strength of the academic and research programme has not been reflected

in the degree of successful application of biotechnology. Mechanisms need to be found to strengthen the co-operation between research institutions internationally, and also the transfer from academia to industry within a country.

27. The potential applications for biotechnology are large. Developing countries are concerned that some of these applications can add another dimension of comparative disadvantage in international economic and trade relations. However, channelling appropriate human and financial resources for biotechnology research and development, encouraging investments in environmentally sound biotechnology projects, avoiding technological obstacles, can strengthen the capacities of developing countries in this field and yield food dividends.

28. The difficulties of monitoring and enforcing a Code of Conduct could be mitigated by increased co-operation of the private sector. This might take the form of a greater level of transparency and accountability, including a demonstration of compliance with regulations. As part of this communication process, the private sector could assist in demystifying biotechnology, thereby enabling more widespread and beneficial implementation. Training and know-how transfer is a vital component of biotechnology transfer, particularly to ensure safe and responsible implementation.

V. POTENTIAL AREAS FOR ACTION

Objectives and Goals

29. The integrated programme on biotechnology should aim at promoting sustainable applications of biotechnology in all of the application areas identified above. The benefits that could be gained in the areas of health, agriculture and environmental management are potentially very great, and it is particularly important to ensure that the widespread application of biotechnological techniques over the longer term is not held back due to mismanagement, accidents or misapplications in the early projects. The benefits cannot be delivered unless the risk are properly contained, and risk assessment and management should be a precursor to biotechnology transfer and application.

30. The objectives of the programme are therefore twofold: to maximise the potential benefits, by setting up mechanisms to identify and promote priority applications of biotechnology; and to develop a sound basis for risk assessment and management that can be applied by all countries, including those countries without significant expertise in biotechnology. These two aspects are dealt with below.

Risk Assessment and Risk Management

Developing Methodologies for Risk Assessment and Management

31. Most of the national and international risk assessment procedures currently in use or under consideration follow four major steps. These are:

(i) Supply of information;
(ii) Review prior to application;
(iii) Describing safety procedures, protocols;
(iv) Monitoring during and after the application.

32. The following main elements of methodologies for risk assessment and risk management are suggested for elaboration:

- Categorisation of containment levels and requirements for the contained use of GMO's;

- Establishment of "case by case" and "step by step" procedures for releases into the environment of GMO's;

- Information requirements, databases;

- Procedures for risk assessment;

- Protocols for actual applications, including safety conditions, transport requirements, training et cetera.

- Monitoring requirements.

Internationalizing Safety Methodologies

33. The level to which safety methodologies can be conducive to environmentally sound management of biotechnology depends, inter alia, on the level of international harmonisation of these methodologies. The purpose of this part of the programme would be to develop an international approach on safety in biotechnology by strengthening and augmenting on-going activities in this area in a co-ordinated way. Suggested elements of the procedures to strengthen and augment on-going activities in this area in a co-ordinated way are:

Disseminating Information

34. In order to avoid duplication of effort in the preparation of safety methodologies, existing national and international guidelines, recommendations and legislation should be collected and disseminated. This information should be made available to countries as well as to regional groups, together with information about available management technology and training facilities. In co-operation with countries and regional groups, the collected material should be translated and adapted to the specific ecological and institutional circumstances of the region. Specific attention should be given to vulnerable ecosystems in tropical areas.

Education and Training

35. Education and training have to be geared particularly to promote environmentally sound and safe applications of biotechnology that will contribute to sustainable development.

Technical Assistance and Co-operation

36. The steps described in the previous paragraphs (making available existing guidelines, adapting guidelines to regional demands, drawing up basic safety guidelines) may take several years before they lead to practical results. Mechanisms must also be set up to offer the possibility of immediate assistance where necessary:

- Some means should be found to provide direct advice upon request on an ad hoc basis. This would include acting as a contact point between the requesting authorities and the existing or future safety committees for genetic modification.

- A prior informed consent procedure for GMO's could be established analogous to the notification system for banned and/or severely restricted toxic chemicals in order to supply developing countries with the information needed for risk management.

Promoting Biotechnology Application

Framework of Opportunities

37. The programme would develop a framework/matrix aimed at maximising potential benefits with the application of biotechnology drawing upon the work carried out, for example, by the World Bank. The matrix would list needs/applications and the availability of specific biotechnology applications. The criteria used to classify biotechnologies and applications could include availability of the technology; appropriate use of the technology, taking into account that the technical level of a solution should match the technical level of a problem; presence of a suitable infrastructure; costs; possible environmental, social and economic side effects and management of risk assessment, monitoring and safety procedures.

38. The matrix should look at short and long term biotechnology applications. A perspective of applications using today's technologies would emphasise commonly available technologies, and realistic and achievable projects that have a high probability of success, since demonstration of short-term benefits is key to the acceptance and success of biotechnology. A longer term projection on the basis of new biotechnologies and applications would identify potential areas where biotechnology could promote large scale changes in agricultural or industrial practice. The opportunities should keep in mind the overall goal of sustainable development, as well as regional priorities, especially the building of indigenous capacity and development of the private sector. The major

components of the programme, which would be part of the UNCED Agenda 21, and would be elaborated for the Third Session, would include:

Detoxification and Waste Treatment

39. Increased application of biotechnologies could be used for microbial conversion of industrial and other wastes into value added products or harmless effluents. Similarly, biotechnology research and application should be accelerated in the detoxification of hazardous wastes.

Biological Control of Pests and Diseases

40. Biotechnological agents could control serious insect pests and diseases affecting agricultural crops. To reduce large scale losses caused by viruses, development of virus-resistant plants through genetic engineering is a promising strategy. Applications of virus resistance to fruits and vegetables represent near-term opportunities for developing countries. Such applications would form an important component of integrated pest management and hence reduce dependency on the use of chemical pesticides.

Crop Biotechnology

41. Biotechnological tools to supplement conventional plant breeding range from tissue culture and micropropagation through to recombinant DNA. Goals for their application include greater yields, crops specially adapted to local conditions, and production of large numbers of plantings of uniformly high standard for large scale crops.

Biomass Production

42. Some tropical tree species do not lend themselves for easy propagation through seed. Tissue culture can help offset this constraint, contribute to the maintenance of genetic resources and help accelerate natural and commercial reforestation programmes. The use of tissue culture could also contribute to the broader goal of modulating global warming and the greenhouse effect through increasing forest capacity to fix carbon dioxide and act as a carbon sink.

Freshwater and Marine Aquaculture

43. Biotechnology can greatly increase fish production by improving fish nutrition, biofertilization and culture of fish food organisms, fish disease diagnosis, in vitro fertilization, cryopreservation of embryos and larval development.

Human Health and Well-Being

44. Potential for biotechnological applications exists in several areas, including development of candidate vaccines, immunodiagnostics, DNA probes for important diseases, production of polyclonal and monoclonal antibodies and drug delivery.

Industrial Biotechnology

45. There are an increasing number of potential and existing industrial applications which include the manufacture of food stuffs, fine chemicals and pharmaceutical products. Depending upon the developmental priorities of a country, appropriate applications could be determined and promoted.

Other Considerations in Application of Biotechnology

46. An integrated strategy for the environmentally sound application of biotechnology should also be elaborated for:

Research and Development Co-operation;

Information Dissemination and Exchange;

Education and Training; and

Promoting Enabling Mechanisms;